

## REMARKS

Claims 1-36 are presently pending in the case. Reconsideration of the present case in view of the remarks herein is requested.

### **Claim rejections under 35 USC §102**

The Examiner rejected claims 1-13, 15, 16, and 28-33 under 35 USC §102(b) as being anticipated by U.S. Patent 5,284,133 to Burns et al (hereinafter Burns et al). The rejection is traversed.

Burns et al does not anticipate independent claim 1, for example. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation. Claim 1 is to an aerosol drug delivery system comprising, *inter alia*, an electronic prevention device which prevents manual actuation of a drug formulation when in an inactive state and which permits manual actuation when an electric current is supplied to place the prevention device in an activated state. This positively recited feature is not disclosed by Burns et al. Burns et al does not disclose a prevention device that prevents manual actuation when in an inactive state. Instead, in Burns et al, a controller activates the lockout mechanism (see column 10 line 28 through column 11 line 38, for example). Since Burns et al does not disclose each and every feature set forth in claim 1, it does not anticipate the claim. Thus, the Examiner is respectfully requested to reconsider the language of claim 1 and withdraw the rejection thereof under 35 USC §102.

The Examiner directs Applicant's attention to column 8 lines 10-20 in support of the position that the lockout mechanism of Burns et al is in an inactive state when preventing actuation. However, the passage referred to discusses a recording feature of the device and does not disclose that which the Examiner purports. Accordingly, the recitation does not serve to show that Burns et al anticipates claim 1.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of the rejection of claims 2-16 which depend from claim 1 and are not anticipated by Burns et al for at least the same reasons as claim 1.

In addition, independent claim 28 is not anticipated by Burns et al. Claim 28 is to an aerosol drug delivery system comprising, inter alia, a control system comprising a locking mechanism that may be in an activate or an inactivate state, wherein the control system controls the opening of a valve such that a valve is only opened when a dosing condition has been satisfied at which time the locking mechanism in the active state. Burns et al does not disclose a locking mechanism in an inactive state. Accordingly, Burns et al does not anticipate claim 28.

Applicant requests withdrawal of the rejection of claim 28 under 35 U.S.C. §102(b). In addition, Applicant requests withdrawal of the rejection of claims 29-33 which depend from claim 28 and are not anticipated by Burns et al for at least the same reasons as claim 28.

### **Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 17-27 under 35 USC §103(a) as being unpatentable over Burns et al. The rejection is traversed.

Burns et al does not render independent claim 17 unpatentable. Claim 17 is to a method of aerosolizing a drug formulation, the method comprising, inter alia, preventing the manual actuation of the aerosolization of the drug formulation with an electronic lockout device by maintaining the lockout device in an inactive state. Burns et al does not teach an electronic lockout device that can be maintained in an inactive state. Since Burns et al does not teach or suggest all claimed elements and because the Examiner has not provided reasoning as to why a modification to Burns et al that would result in a

device encompassed by method of claim 17 would be obvious, the Examiner has failed to establish a *prima facie* case under 35 USC 103(a). Accordingly, Applicant requests withdrawal of the rejection.

For at least these reasons, claim 17 is not properly rejectable under 35 USC §103(a) as being unpatentable over Burns et al. Furthermore, a modification to Burns et al that would result in the claimed method is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that a modification could be applied, with a reasonable likelihood of success, to Burns et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined well-known teachings in a manner that would result in the invention of claim 17 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that effective drug delivery control can be achieved with minimized power consumption, as discussed on page 9 line 3-15 of the specification, using the method of claim 17. Thus, claim 17 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 17 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 18-27 which depend from claim 17 and are not rendered unpatentable by Burns et al for at least the same reasons as claim 17.

The Examiner rejected claims 14 and 34-36 under 35 USC §103(a) as being unpatentable over Burns et al in view of U.S. Patent 4,934,358 to Nilsson et al (hereinafter Nilsson et al). The rejection is traversed.

Claims 14 and 36 are not rendered unpatentable by Burns et al and Nilsson et al. Claims 14 and 36 depend from claim 1 and include all the limitation thereof. Nilsson et al does not make up for the deficiencies of Burns et al with regard to claim 1, i.e. Nilsson et al does not teach or suggest a prevention device that prevents manual actual

when in an inactive state. Since neither Burns et al nor Nilsson et al disclose, teach or suggest all positively recited features in claim 1, Burns et al do not render claim 1 unpatentable. For at least the same reason, Burns et al and Nilsson et al do not render claims 14 and 36, both of which depend from claim 1, unpatentable.

Burns et al and Nilsson et al also do not render independent claim 34 unpatentable. Claim 34 is to a method comprising, *inter alia*, preventing the aerosolization of a formulation with a lockout device when the lockout device is in an inactive state. Neither Burns et al nor Nilsson et al disclose, teach or suggest a lockout device that prevents aerosolization in an inactive state. Thus, Burns et al and Nilsson et al do not render claim 34 unpatentable.

For at least these reasons, claim 34 is not properly rejectable under 35 USC §103(a) as being unpatentable over Burns et al in view of Nilsson. Furthermore, a modification to Burns et al that would result in the claimed method is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that a modification taught by Nilsson could be applied, with a reasonable likelihood of success, to Burns et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined well-known teachings in a manner that would result in the invention of claim 34 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Furthermore, Applicant has unexpectedly found that effective drug delivery control can be achieved with minimized power consumption, as discussed on page 9 line 3-15 of the specification, using the method of claim 34. Thus, claim 34 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 34 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claim 35 which depend from claim 34 and is not rendered unpatentable by Burns et al and Nilsson et al for at least the same reasons as claim 34.

## Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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By: 

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